REMARKS

I. Status of the Application

Claims 1, 2, 4-9, 14, 20, 21 and 24 are presently pending in the application. Claim 14 has been cancelled without prejudice to the filing of any appropriate continuation applications. Claims 1, 2, 4-9, 14, 20, 21 and 24 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claim 14 remains rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement.

Applicants have amended the claims under consideration to more clearly define and distinctly characterize Applicants' novel invention. Claim 1 was amended to remove the language "or a nucleic acid sequence functionally equivalent thereto, and comprising Ets binding sites at about nucleotides 3223, 3451 and 3520 of SEQ ID NO:5 and an Sp-1 binding site at about nucleotide 3274 of SEQ ID NO:5."

Applicants respectfully submit that the amendments presented herein contain no new matter and present no new issues requiring further search. Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place the case in condition for allowance.

II. The Specification Provides Adequate Written Description for the Pending Claims

At page 2 of the instant Office Action, claims 1, 2, 4-9, 14, 20, 21 and 24 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that, based on the limited teaching of the specification, the description of the core structure of the claimed promoter is not sufficient for supporting the claimed genus of nucleic acids, especially the functional equivalents. Applicants respectfully traverse this rejection in view of the amended claims now presented.

Applicants respectfully submit that the specification provides adequate written of the claimed nucleic acid sequence, and that one of skill in the art would readily understand the structure of the claimed nucleic acid sequence based on Applicants' teachings. Without acquiescing to the rejection, Applicants respectfully submit that claim 1 has been amended to remove reference to functional equivalents. Amended claim 1 and claims depending therefrom are presently directed to an isolated or recombinant nucleic acid sequence ***comprising a promoter region encoding nucleotides 3200 to 3556 of SEQ ID NO:5***, wherein said nucleic acid sequence allows expression of a nucleic acid sequence of interest operably linked to said promoter in a cancer cell in an epithelium-selective manner.

The Office Action invites Applicants to clarify the relationship between nucleotides 3200 to 3556 of SEQ ID NO:5 and the 336 base pair sequence between base pair 442 and base pair 778. In response, Applicants respectfully direct the Examiner's attention to Figure 1, which depicts SEQ ID NO:5 and each of the deletion mutants. The constructs containing the first 442 base pairs of the promoter region ($p39^{E11-1}$) and the first 778 base pairs of the promoter region ($p39^{E4-1}$) are depicted. The beginning and end of each deletion mutant is marked with a "["or a "]," respectively. Nucleotides 3200 to 3556 are located within the region between $p39^{E7-2}$ and $p39^{E11-1}$.

The Office Action states that it is unpredictable whether the claimed sequence can direct epithelial expression for a heterologous gene. Applicants respectfully disagree. Applicants have experimentally demonstrated that ***five*** different truncation mutants containing the claimed promoter region can direct ***epithelial-specific expression*** of a heterologous green fluorescent protein (See, e.g., Figure 1 and Figure 2 ($p39^{E4-7}$, $p39^{E17-1}$, $p39^{E15-2}$, $p39^{E7-2}$ and $p39^{E4-1}$)). Further, Applicants have experimentally demonstrated that the p39E promoter can express luciferase and cytosine deaminase (CD) (paragraph [0077] of the published application; See also

McLaughlin et al., Attachment A, page 607, right column, first full paragraph; Table 2) as well as the thymidine kinase (TK) suicide gene (McLaughlin et al., page 608, right column, first full paragraph; Figure 5).

Based on Applicants' teachings of heterologous gene expression by various promoter constructs as well as Applicants' demonstration that ***four*** different heterologous genes can be expressed by the p39E promoter, one of skill in the art would readily predict that the claimed nucleic acid sequence would be able to drive the expression of a variety of different nucleic acid sequences of interest operably linked to the promoter as claimed by Applicants. Applicants' teachings should apply to all heterologous genes, and, based on Applicants' teachings, it would be a routine matter for one of skill in the art to express any number of heterologous genes using the claimed promoter region. In view of Applicants' teachings, one of skill in the art would have no reason to doubt that expression of a heterologous sequence would be achieved, and the Office Action has provided no evidence that a nucleic acid sequence of interest operably linked to the claimed promoter would fail to be expressed.

For at least these reasons, the instant specification provides adequate written description for the claimed invention. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection of claims 1, 2, 4-9, 14, 20, 21 and 24 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

III. Enablement Rejection

At page 4 of the instant Office Action, claim 14 remains rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that, based on the limited teaching of the instant specification and the art-recognized unpredictability, the claimed medicament is not enabled.

Applicants respectfully traverse this rejection. Without acquiescing to this rejection, and solely to expedite prosecution, Applicants have cancelled claim 14. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 14 under 35 U.S.C. § 112, first paragraph, as lacking enablement.

IV. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone Applicants' attorney at the number below.

Respectfully submitted,

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